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PRESS RELEASE
November 26, 2024

New DiviTum® TKa data to be presented at SABCS that significantly broaden the addressable market

Biovica, active in cancer monitoring, announces that seven abstracts based on studies using the blood test DiviTum TKa will be presented at the world's largest breast cancer meeting, San Antonio Breast Cancer Symposium (SABCS) on December 10-13, 2024. Two of the abstracts validates DiviTum TKa in the adjuvant setting (early breast cancer), which will open a new market opportunity for Biovica, increasing the addressable market within breast cancer with $3BUSD / year on key markets (US, Europe and Japan).

The new data reinforce DiviTum TKa as a monitoring and predictive test for hormone receptor-positive (HR+) patients with both metastatic and early breast cancer (adjuvant) treated with CDK4/6 inhibitors, the most prescribed drug class for this patient population.

"The SABCS-symposium is an excellent opportunity to share the great results achieved in clinical trials with DiviTum TKa and provides exposure to around 11,000 participants. This year with a record of seven abstracts. We are also very excited about the strong adjuvant (early breast cancer) data, indicating a vast market opportunity for us plus the possibility to improve care for even more breast cancer patients," said Anders Rylander, CEO of Biovica.

More about the

Abstract Title	**Institution**	**Patient Population**	**Key Findings**
"Interrogating serum thymidine kinase activity with CDK4/6 inhibitor-based therapies: real-world experience in the metastatic and adjuvant setting."	Roswell Park, US	HR+ MBC 1ST LINE HR+ ADJUVANT BC ABEMA	**TKa is predictive in adjuvant BC** • An on therapy TKa level of <50 DuA is predictive for a >20 month response to therapy in CDK4/6i treated pts diagnosed with HR+ MBC • An on-therapy TKa level of >243 is predictive for <8 months of response to therapy • Adjuvant BC pts treated with abemaciclib had a highly significant reduction in TKa between BL and C1 /C2 • Elevated TKa levels were observed with disease recurrence

"Evaluation of proliferation biomarker serum thymidine kinase activity and prediction of early relapse in HR-positive HER2 negative high-risk early breast cancer: Analysis from the PENELOPE-B trial."	The German Breast Cancer Group, Germany, and US	HR+ ADJUVANT BC PALBO	**TKa is prognostic in adjuvant BC** • In PENELOPE-B, BL TKa values >250 DuA were prognostic for early relapse within the 1st year of adjuvant therapy • CPS-EG scores, in contrast, were not prognostic. • Pts with early disease relapse also had an increase in TKa levels at the time of recurrence.
"ctDNA and serum thymidine kinase activity as tools to stratify ER+/HER2- metastatic breast cancer patients treated with endocrine therapy and CDK4/6 inhibitors: preliminary results of the TIRESIAS trial."	Hospital of Prato, Italy	HR+ MBC 1ST LINE	**TKa offers an attractive alternative to ctDNA** • Circulating tumor DNA (ctDNA) and thymidine kinase activity (TKa) give complimentary information • TKa and ctDNA dynamic changes are concordant • TKa offers a cost-effective and easier alternative to ctDNA for non-invasive monitoring of early response to therapy
"Thymidine kinase activity as a prognostic biomarker for first-line CDK4/6 inhibitor efficacy in the Personalised Disease Monitoring in Metastatic Breast Cancer (PDM-MBC) Study."	Jönköping Hospital Sweden, Christie in Manchester, UK	HR+ MBC 1ST LINE	**TKa levels are prognostic for CDK4/6i efficacy in HR+ MBC** • Baseline (BL) TKa >250 DuA associated with shorter PFS (13.5 mo vs not reached) and OS (30.3 vs 51.8 mo) in 1st line CDK4 /6 inhibitor pts • A TKa value >100 DuA at any cycle 1 timepoint (BL, D15, D28) predicted for a significantly worse PFS and OS vs staying below 100 DuA at all 3 timepoints.

"The Role of Serum Thymidine Kinase 1 (TK1) as a Prognostic Factor in Luminal HER2 Negative Breast Cancer."	IRBLeida, Spain	HR+ Early breast cancer pre/post surgery HR+ MBC 1ST LINE	**TKa is a prognostic biomarker in luminal BC** • EBC pts with high TKa also have a high OncotypeDx score. • MBC pts who had an on-therapy increase in TKa had progression in 3-6 mo • MBC pts who had an on-therapy decrease in TKa had a response lasting greater than 3-6 mo
"Thymidine kinase activity as a prognostic and predictive biomarker in the Phase II PACE trial of CDK4/6 inhibition beyond progression ."	Dana Farber Cancer Institute, US	HR+ MBC 2ND LINE - PALBO	**TKa can predict 2nd line CDK4/6i benefit** • There currently is no existing biomarker to predict the benefit to a CDK4/6i following progression on a previous CDK4/6i • High C2D1 on-treatment TKa (>250 DuA) was associated with a lack of response to palbociclib beyond progression on a prior CDK4/6i • Authors conclude TKa could facilitate clinical decisions in this context
"Thymidine kinase activity as a predictive biomarker for benefit to a second line CDK4/6 inhibitor: analysis from the MAINTAIN trial.	Emory, US	HR+ MBC 2ND LINE RIBO	**TKa can predict 2nd line CDK4/6i benefit** • TKa levels on C2D1 significantly predicted for the benefit to ribociclib after progression on a prior CDK4/6i • TKa <250 DuA had a PFS of 10.9 mo on ribociclib • TKa >250 DuA had a PFS of 2.7 mo on ribociclib

List of abbreviations
ABEMA The CDK4/6 inhibitor from Eli Lilly called Abemaciclib
BC Breast Cancer
BL Base Line – prior to treatment
C1 treatment cycle 1
C2 treatment cycle 2
C2/D1 treatment cycle 2, day 1
CDK4/6i CDK4/6 inhibitor treatments
CPS-EG score: The CPS (Clinical and Pathological Score) + EG (Estrogen and Grade) scoring system
ctDNA circulating tumor DNA
D15 Day 15
D28 Day 28
DuA DiviTum units of activity
EBC early breast cancer
HER2 Human Epidermal growth factor Receptor 2
HR Hormone receptor
HR+ Hormone receptor-positive
MBC Metastatic breast cancer
mo months
OS overall survival
PALBO The CDK4/6 inhibitor from Pfizer called Palbociclib
PFS progression-free survival
Pts Patients
RIBO The CDK4/6 inhibitor from Novartis called Ribociclib
TKa Thymidine Kinase activity

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Biovica – Treatment decisions with greater confidence

Biovica develops and commercializes blood-based biomarker assays that help oncologists monitor cancer progression. Biovica's assay, DiviTum® TKa, measures cell proliferation by detecting the TKa biomarker in the bloodstream. The assay has demonstrated its ability to provide insight to therapy effectiveness in several clinical trials. The first application for the DiviTum® TKa test is treatment monitoring of patients with metastatic breast cancer. Biovica's vision is: "Improved care for cancer patients." Biovica collaborates with world-leading cancer institutes and pharmaceutical companies. DiviTum® TKa has received FDA 510(k) clearance in the US and is CE-marked in the EU. Biovica's shares are traded on the Nasdaq First North Premier Growth Market (BIOVIC B). FNCA Sweden AB is the company's Certified Adviser. For more information, please visit: www.biovica.com

This information is information that Biovica International is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-11-26 08:00 CET.

Attachments

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